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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,305	05/25/2001	Peter Lea	874-35/AMK	4707

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EXAMINER	
DIRAMIO, JACQUELINE A	

ART UNIT	PAPER NUMBER
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/866,305	LEA ET AL.	
	Examiner	Art Unit	
	Jacqueline DiRamio	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35* is/are pending in the application.

4a) Of the above claim(s) *36-98* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-35 in the reply filed on February 10, 2004 is acknowledged.

Claims 36-98 are withdrawn from further consideration by the examiner under 37 CFR 1.142(b), as being drawn to non-elected inventions and are acknowledged as cancelled by applicant.

Specification

The disclosure is objected to because of the following informalities:

1) On page 13, Figure 7 is referred to on line 14, but this figure does not exist, only Figures 7A and 7B. Also, referred to Fig. 7 on line 19 of page 16, line 5 of page 22, line 17 of page 29, and line 18 of page 30.

2) On page 14, edge 59 is referred to on lines 10 and 18, but this edge 59 does not exist in Figs. 4 or 5 as disclosed.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected as being vague and indefinite for the recitation of "major" because it is unclear what "major" refers to.

Claim 10, "the major planar portion" lacks antecedent basis.

Claim 11, "the exterior surface" and "the interior surface" lack antecedent basis.

Claims 12 and 23, "the chamber" lacks antecedent basis.

Claims 16 and 25, "the planar bottom wall" lacks antecedent basis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 – 4, 12, 13, 15 – 18, 21, 23 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmer (US 6,592,815) in view of Shareef et al. (US 6,338,969).

Zimmer teaches an analytical test element for determining an analyte in a liquid sample. The test element contains a base (planar base) with a planar wall and a cover containing a recess (cavity) wherein a detection element (insert) is received (see Figures 1 and 2 in particular). A first surface (planar portion) of the cover, including the detection element, is separated from the base's surface (major planar wall) by a

distance to define a capillary-active region (space), which is effective to cause capillary flow of a fluid sample at a sample application opening (entrance) into the capillary-active region (space) (see column 3, lines 4-8 and Figure 2 in particular). The detection element (insert) comprises a second surface containing a detection zone (reading portion) for analyzing the fluid sample. The detection element (insert) further contains a sample application zone (input portion), which is in communication with the sample application opening (entrance) to the capillary-active region (space) (see Figure 1 in particular). The detection zone is arranged next to sample application zone in a way that enables planar liquid transfer (see column 5, lines 56-66 in particular). There is a passage from the sample application opening (entrance) to the sample application zone (input portion) of the detection element (insert) via the capillary-active region (see Figure 2 in particular). The detection element can be equipped with a filter, such as a semipermeable membrane (porous membrane), prior to the detection zone (proximate to input portion and within passage) to exclude interfering sample components (see column 6, lines 12-31 in particular). The detection zone contains reagents, which react with the analyte, if present, to form a signal either visually observable or detected through an instrument means (see column 7, lines 51-62 in particular). The detection element (insert) is contained or integrated (press-fit) within a recess (chamber) in the cover, which defines the volume of the capillary-active region (space) when attached to the base (see column 7, lines 65-67 and column 8, lines 1-9 in particular). The detection element (insert) further allows for the detection zone (reading portion) to be transparent for the optical observation of the detection reaction (see column 5, lines 28-

37 in particular). Also, the capillary-active region (space) can be narrowed through the configuration of the cover and base to slow the capillary force after fluid passes the sample application zone (input portion) (see column 8, lines 1-9 in particular). This narrowing can be created through the cover or base and could be conceived as a tapering of the cover towards the passage defined by the sample application opening (entrance) and sample application zone (input portion) (see Figure 2).

Zimmer fails to teach a side wall transverse to and surrounding the base's planar wall to define a cavity for receiving the insert. Zimmer further fails to teach that the sample application zone (input portion) is contained on the second surface of the detection element (insert).

Shareef et al. teach an assay test system wherein a test strip (insert) and a thermally conductive material (insert) are received within a well (cavity) defined within the casing's bottom (major planar wall), wherein the test strip allows for the test fluid to flow by capillarity (see column 3, lines 32-65 in particular). With respect to Applicant's claims 21 and 31-33, the well (cavity) has side walls perpendicular to the base, comprising a plurality of walls extended from the base, which define a well (cavity) recessed into the casing's bottom (base) (see Figure). Shareef et al. teach the benefit of creating a well within the assay system's casing to create a hollow chamber for efficiently holding the test strip and thermally conductive material. Shareef et al. further teach a sample application port, wherein sample is added to the application region of the test strip (both sample application port and application region comprise the input portion). The application port and region are located on the top surface (second

surface) of the cover and test strip, which allows for easy sample application into the device and is a conventional embodiment for an assay device. With respect to Applicant's claims 13, 17 and 18, the application port embodies a tapered surface comprising an upstanding wall circumscribing the application region (input portion) (see Figure).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to create a cavity within the base of the test element of Zimmer as taught by Shareef et al. because Shareef et al. teach the benefit of creating a well (cavity) to efficiently hold a test strip and thermally conductive material (insert). It also would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the input portion of the device of Zimmer on an opposing second surface as taught by Shareef et al. because it is a conventional embodiment for sample application known in the art.

Claims 5 – 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmer (US 6,592,815) and Shareef et al. (US 6,338,969) as applied to claims 1 – 4, and further in view of Caldwell (US 5,912,116).

Zimmer and Shareef et al. have been discussed above, but fail to teach the use of a dynamic capillary filter comprising a plurality of particles wherein the particles are microspheres supported by a porous membrane.

Caldwell teaches methods for measuring analytes using barrier webs wherein the webs can be formed of various compositions including beads of spherical

(microspheres) or other shapes (column 58, lines 54-60 in particular). The porosity of the barrier webs can be controlled and therefore used as exclusion filters (dynamic capillary filter), which trap microorganisms that are greater than the pore size of the barrier web. The barrier web can further be used with a bioactive surface to further control what particles can pass through the web (see column 59, lines 1-9 in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the beads (microspheres) taught by Caldwell with the semipermeable membrane filter (porous membrane) used in Zimmer's detection element because Caldwell teaches the benefit of using barrier webs, in the form of spherical beads, as exclusion filters because the porosity can be controlled and therefore, what particles can pass through the web is controlled.

Claims 14, 20, 22 and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmer (US 6,592,815) and Shareef et al. (US 6,338,969) as applied to claim 1, and further in view of Oberhardt (US 5,658,723).

Zimmer and Shareef et al. further fail to teach that the detection element (insert) and/or the base (major planar wall) are transparent. Zimmer and Shareef et al. fail to teach the use of reflective layers on opposite sides of the capillary-active region (space), particularly placing the layers on the underside of the cover (planar portion) and on the base (planar bottom wall) wherein one of the surfaces defines an inlet for radiation and the other an outlet, and positioning the inlet and outlet to reflect radiation

entering the inlet multiple times between the reflective surfaces prior to exiting the capillary-active region (space).

Oberhart teaches an immunoassay system with a base, overlay and cover wherein the distance between the cover and base is sufficient to draw a fluid sample into the reaction space by capillary action (see column 10, lines 1-20 in particular). The base (major planar wall), overlay and cover are all typically created out of a transparent material for optical observations of reactions occurring within the assay system (see column 9 and 10, lines 50-67 in particular). With respect to Applicant's claims 22 and 27 – 30, reagents used in Oberhart's assay system are either in dry form (dry matrix) or contained within a gel, depending on the assay performed, and placed within the capillary space created between the cover and base (column 3, lines 56-67 and Figures 39 and 43 in particular). Oberhart's assay system further utilizes reflective layers wherein one is placed on top of the overlay (planar portion) and a corresponding layer is placed on the base (planar bottom wall), therefore, the reflective layers are on opposite sides of the capillary space. This placement allows for total internal reflection of light (radiation) passing through the sides of the cover and base (defining an inlet) and exiting though the opposite edges of the cover and base (defining an exit) (see column 11, lines 20-27 and column 12, lines 46-59 in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the device taught by Zimmer, the use of a transparent base and/or cover and inlay (insert) as taught by Oberhart because Oberhart teaches the use of transparent materials in an assay device for optical

observation of reactions occurring. It also would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the device taught by Zimmer the reflective layers and placement as taught by Oberhart, because Oberhart teaches the benefit of using and placing these layers opposite from the capillary space to ensure total internal reflection of light (radiation).

Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmer (US 6,592,815) and Shareef et al. (US 6,338,969) as applied to claim 1, and further in view of Eisinger et al. (US 4,943,522).

Zimmer and Shareef et al. further fail to teach the use of legs either on the first surface of the cover and detection element (insert) or on the base (major planar wall) for supporting the detection element (insert).

Eisinger et al. teach a lateral flow assay wherein columns (legs) are created on the base of the device to effectively support a lateral flow membrane (insert) within the device (see Figure 4 and column 12, lines 51-68 in particular). Although the columns were only created on the base, it would have been obvious to position them on a different surface, such as the cover, depending on the embodiment of the device.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the columns (legs) as taught by Eisinger et al. with the device taught by Zimmer, because the Eisinger et al. teach the benefit of using columns (legs) within a device because of their ability to effectively support a membrane (insert).

Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmer (US 6,592,815) and Shareef et al. (US 6,338,969) as applied to claim 1, and further in view of Deisboeck et al. (US 6,602,701).

Finally, Zimmer and Shareef et al. fail to teach a lid slidably coupled to the base for selectively covering the sample application zone (input portion).

Deisboeck et al. teach a cell-growth assay device wherein a cover or lid is utilized that can be slidable or slides into place over top of the device through a ridge created in the device. The cover or lid creates a tight fit or seal between itself and the device and also protects the cells growing within test chambers found in the device (see column 7, lines 45-64 and column 10, lines 1-6 in particular).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include in the device taught by Zimmer a slidable lid as taught by Deisboeck et al. because Deisboeck et al. teach the benefit of using a sliding cover or lid to create a seal and to protect the various assay components.

Allowable Subject Matter

Claims 9 – 11 are allowed.

The following is a statement of reasons for the indication of allowable subject matter: the prior art neither teaches nor suggests a device utilizing a porous membrane

supporting a plurality of particles in a passage wherein the passage extends from the second surface to the first surface of the insert, with an entrance at the second surface and exit at the first surface; and connecting the porous membrane to the second surface, covering the exit of the passage to prevent passage of particles out of the passage through the exit.

Claims 9-11 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacqueline DiRamio whose telephone number is 571-272-8785. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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06/21/05